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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/621,565	07/21/00	SEIBERG	M JBP0510

AUDLEY A CIAMPORCERO JR ESQ
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK NJ 08933-7003

HM22/0810

EXAMINER

SEIDLECK, B

ART UNIT	PAPER NUMBER
1615	6

DATE MAILED:

08/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/621,565	Applicant(s) SEIBERG ET AL.	
Examiner Brian K. Seidleck	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-52 is/are pending in the application.
4a) Of the above claim(s) 23-52 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-22 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) Interview Summary (PTO-413) Paper No(s). _____
- 19) Notice of Informal Patent Application (PTO-152)
- 20) Other:

Election/Restrictions

1. Applicant's election with traverse of the restriction requirement in Paper No. 4 is acknowledged. The traversal is on the ground(s) that the search would not pose any undue burden. This is not found persuasive because each group is distinct, and relates as a product and process of use. The product, in the instant case, can be used in unrelated applications, such as sunscreens and anti-cancer. The search required for the product is not required for the process of use.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 23-52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 4.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 1 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The specification provides for the topical application of soy extract, for the reduction of hair growth. However, the present claim language, reads on the topical application of said extract, to increase hair growth, because the method is for “effecting changes”. Applicant is requested to distinctly claim their invention, namely the method of reducing hair growth or hair follicle size with the topical application of a soybean extract.

3. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. A method for reducing hair growth and hair follicle size with the topical application of an soybean extract are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Applicant’s disclosure does not support other methods for effecting change in hair such as increasing hair growth or increasing hair follicle size.

4. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the reduction of hair growth or hair follicle size with the topical application of soybean extract, does not reasonably provide enablement for the treatment of the hair with any extract from botanical families such as *leguminosae*, *solanaceae*, *gramineae* or *cucurbitaceae*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. Undue experimentation would be placed on an artisan of ordinary skill in the art to

extract the literal thousands of plant species claimed and topically applying said extract to determine the pharmacological effects.

5. Claim 2 recites the limitation "extract" in line 1. There is insufficient antecedent basis for this limitation in the claim.

6. Claim 18 is rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for treatment of pseudofolliculitis barbae, does not reasonably provide enablement for its prevention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The specification provides no evidence that the composition effectively prevents the claimed disorder. Prevention is for an indefinite period, while the specification provides support for the treatment of this disorder for definite periods of time.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless – (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Kose Corp (JP 5-25027). Kose reads on the topical application of an extract of the *cucurbitaceae* family, useful

as a hair growth inhibitor. See entire translation. It is the examiner's position, that said extract inherently contains serine protease inhibitors and isoflavones, since the extract inhibits hair growth. Other ingredients include other hair inhibitors and cosmetic additives, and the formulations may be a lotion, cream, ointment, etc.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Kose Corp (JP 5-25027) or Styczynski et al (U.S. Pat. No. 5,958,946).

Kose discloses the topical application of an extract of the *cucurbitaceae* family, useful as a hair growth inhibitor. See entire translation. It is the examiner's position, that said extract inherently contains serine protease inhibitors and isoflavones, since the extract inhibits hair growth. Other ingredients include other hair inhibitors and cosmetic additives, and the formulations may be a lotion, cream, ointment, etc. As to the claimed addition of one or more isoflavones, the examiner relies on the additional teachings of Styczynski, wherein the reference teaches the topical application of an isoflavone to reduce hair growth. See claims. One or

ordinary skill in the art would have expected an additive effect (i.e. reduction of hair growth) with the combination of one or more agents known to reduce hair growth.

Correspondence


11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian K. Seidleck whose telephone number is (703) 305-4448. The examiner can normally be reached on M-F (6:30am - 5:00pm) Every Wednesday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Brian K. Seidleck
Patent Examiner
Art Unit 1615

BKS
August 6, 2001


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER/1600